REMARKS

Previous Restriction Requirement

Claims 12-21, 32-39, and 42-44 were withdrawn from consideration due to Applicant's prior election to a restriction requirement.

Applicant has cancelled these claims from the application. Applicant reserves the right to pursue these claims in one or several divisional or continuing applications.

Objection to the Specification

The Examiner has objected to the specification noting that the serial numbers of the applications in the related applications section should be supplied.

Applicant has added the serial numbers as suggested by the Examiner.

Applicant requests the Examiner to withdraw the objection.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 4, 7, 10, 22, 29, and 40 are rejected under 35 U.S.C. § 112, second paragraph.

The Examiner has stated that the recitation of the "extrusion material" is ambiguous because the claims recite extrusion material for the inner and outer layers and the coating of the conductor.

Applicant has amended the identified claim language to note that the extrusion material refers to "at least the extrusion material of the inner and outer layers."

Applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 102

Claims 1, 3-4, 6-7, 9-10, 22-23, 26-29, 31, and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,476,495 to Kordis (hereinafter referred to as "Kordis").

Claims 4-5, 7-8, 10-11, 22, 24-25, and 40-41 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,857,997 by Cimino et al. (hereinafter referred to as "Cimino").

Claims 1, 4-11, 22-23, 24-29, 31, and 40-41 are cancelled without prejudice. Accordingly, the rejection of these claims is not addressed herein.

Claim 3 has been amended to depend from claim 2 (which is discussed below).

Rejections under 35 U.S.C. § 103(a)

Claims 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kordis in view of Cimino.

Claim 30 is cancelled without prejudice. Accordingly, the rejection of this claim is now moot.

Claim 2

Applicant notes that although the Examiner indicates in the "Office Action Summary" that claim 2 is rejected, claim 2 is not specifically addressed anywhere in the Office Action itself. In particular, there is no rejection in the Office Action that refers to claim 2. *See* Office Action, pages 2-6.

Because claim has not been rejected under any statutory basis, Applicant has rewritten claim 2 in independent form. Applicant has also included additional limitations in claim 2. The amendment of claim 2 is fully supported by the original application. No new matter has been entered.

Because there is no rejection of claim 2 in the Office Action, Applicant respectfully requests the Examiner to allow claim 2 and dependent claim 3 (which now depends from claim 2).

Additionally claim 2 recites, in part:

> forming the lead body assembly, wherein the formed lead body assembly comprises a solid matrix of fused extrusion material and wherein the at least one conductor is embedded within the solid matrix, wherein the forming step further comprises the steps of:
>
> placing heat shrink tubing over the lead body assembly;
>
> heating the lead body assembly to melt the extrusion material of at least the inner and outer layers;
>
> compressing the melted extrusion material around the at least one conductor with the heat shrink tubing;
>
> cooling the lead body assembly to form the lead body, wherein the inter-layer discontinuity is removed along a substantially length of the lead body after the cooling is performed; and
>
> removing the heat shrink tubing from the lead body;

Kordis is merely directed to a catheter in which groups of wires are wound about a center tube and Teflon plastic tape 134 is wound over the groups of wires to provide an insulation layer. *See* Kordis, col. 13, lines 59-65 and col. 14, lines 9-12. Kordis does not teach or suggest the lead manufacturing process recited in claim 2.

Although Cimino discloses using a "heat shrinkable thermoplastic tubular member," Cimino discloses a fundamentally different manufacturing process than recited by claim 1. Specifically, Cimino discloses a catheter that includes reinforcing layer 27. Layer 27 comprises multi-filament strands 28 within a polymeric matrix 29. Col. 6, lines 42-51. An outer polymeric jacket or sleeve is physically positioned over layer 27. Col. 10, lines 38-42. The sleeve is a two-part structure that includes jacket 26 and "a heat shrinkable tubular element." *Id.* Hot air is applied to shrink the heat shrinkable tubular element. The purpose of the heat shrink tube is to "press the thermoplastic tube against the exterior of the reinforcing layer 27 to secure the jacket 26 thereto." Col. 10, lines 37-46.

Thus, it is seen that the heat shrinkable member in Cimino is utilized to facilitate the physical assembly of the various tubular elements. Specifically, the original thermoplastic tube for jacket 26 has an inner diameter that is greater than the outer diameter of layer 27 to

ease the positioning of jacket 26 over layer 27. The heat shrink material enables the inner diameter of jacket 26 to be decreased to secure it against layer 27.

There is simply no subject matter in Cimino that teaches or suggests causing extrusion material of an inner layer and outer layer to assume a melted state and applying a heat shrink tubing so as to create a solid matrix of fused extrusion material as recited by claim 1. Specifically, in the finished catheter product of Cimino, layers 26 and 27 remain structurally distinct layers that possess an inter-layer discontinuity as shown in FIG. 3 of Cimino.

Additionally, Applicant notes that the filaments in layer 27 are not utilized as conductors that are electrically coupled to an electrode.

Thus, Kordis and Cimino (either alone or in combination) do not teach or suggest the subject matter of claim 2. Therefore, claim 2 is patentable over these references. Claim 3 depends from claim 2 and is likewise patentable over these references.

New Claims

Applicant has added new claims 45-50. Claims 45-50 are fully supported by the original application. No new matter has been entered.

Claim 45 recites, in part:

> forming the lead body assembly, wherein the formed lead body assembly comprises a solid matrix of fused extrusion material and wherein the plurality of conductors are embedded within the solid matrix, wherein the forming step further comprises the steps of:
>
> (a) placing heat shrink tubing over the lead body assembly;
>
> (b) heating the lead body assembly to melt at least the extrusion material of the inner layer and the outer layer;
>
> (c) compressing the melted extrusion material of the inner layer and the outer layer around the plurality of conductors with the heat shrink tubing;
>
> (d) cooling the lead body assembly to form the lead body, wherein the inter-layer discontinuity is removed along a substantially length of the lead body after the cooling is performed; and
>
> (e) removing the heat shrink tubing from the lead body.

Claim 48 recites, in part:

> forming the lead body assembly, wherein the formed lead body assembly comprises a solid matrix of fused extrusion material and wherein the plurality of

conductors are embedded within the solid matrix, wherein the forming step further comprises the steps of:

(a) heating the lead body assembly to melt at least the extrusion material of the inner layer and the outer layer;

(b) concurrently with the heating, uniformly compressing the melted extrusion material of the inner layer and the outer layer around the plurality of conductors;

(d) cooling the lead body assembly to form the lead body, wherein the inter-layer discontinuity is removed along a substantially length of the lead body after the cooling is performed; and

(e) removing the heat shrink tubing from the lead body.

For the reasons discussed above in regard to claim 2, Applicant respectfully submits that claims 45 and 48 are patentable over Kordis and Cimino. Claims 46-47 and 49-50 respectively depend from base claims 24 and 48 and, hence, inherit all limitations of their base claim. Claims 46-47 and 49-50 are likewise patentable over Kordis and Cimino.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw.

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Respectfully submitted,

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